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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,328	08/21/2003	Rodolfo R. Llinas	05986/100K521-US1	7569
7278	7590	01/09/2007		
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			EXAMINER NATNITHADHA, NAVIN	
			ART UNIT	PAPER NUMBER
			3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,328	LLINAS, RODOLFO R.	
	Examiner	Art Unit	
	Navin Natnithithadha	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>20061005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1, 10, and 18 have been amended. Claims 37 and 38 have been cancelled. Claims 39 and 40 have been added. Claims 1-36, 39, and 40 are pending.
2. The 35 U.S.C. 112, second paragraph, rejections to claims 10-17 are WITHDRAWN in view of the Amendment.

Response to Arguments

3. Applicant's arguments with respect to claims 1-36, 39, and 40 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-5, 10-12, 18, 26, 28, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy, US 4,852,573 A ("Kennedy").

Claims 10-12, 28, and 39: Kennedy teaches a device for sensing the activity of neural tissue (see Abstract), comprising: a catheter (wire) 14; an electrode (end of wire 14) 26 that is smaller than 5 microns in diameter ("wire 14 can be of any convenient diameter, preferably 1-1000 microns", see col. 4, ll. 23-24), the electrode 26 being deployed from the catheter in a blood vessel proximate to the neural tissue ("an electrode implantable

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in the brain or other area of neural activity", see Abstract), wherein a signal on the electrode is monitored by way of a wire 14 connected to the electrode, the signal being indicative of the electrical brain activity of the neural tissue ("to provide long term recording of electrical signals", see Abstract); a signal processor, an amplifier, a digital converter ("reference to a recording device 33 should be understood to include signal transmission and reception devices where the signal information is, at some point, transferred by radiowaves or fiber optics", see col. 4, ll. 49-52).

Claims 1-5, 18, 26, and 30: Kennedy teaches a method of sensing the activity of neural tissue, comprising: placing an electrode in a blood vessel proximate to the neural tissue at a point upstream or downstream of a junction with another blood vessel ("Electrode 10 is implanted in a part of the body which gives access to neural activity and corresponds to the area of interest for measurement", see col. 5, ll. 47-49), the electrode 10/26 being smaller than 10 microns in diameter ("wire 14 can be of any convenient diameter, preferably 1-1000 microns", see col. 4, ll. 23-24); and monitoring a signal on the electrode by way of a wire 14 connected to the electrode 10/26, wherein the signal is indicative of the electrical brain activity of neural tissue (see Abstract), applying a stimulus to the neural tissue (see col. 5, ll. 37-41); and monitoring a signal on the electrode 10/26 (using record device 33).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 14-16, 27, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy, as applied to claims 1, 10, and 18 above, and further in view of Howard, et al, US 5,843,093 A ("Howard").

Claims 14-16, 27, 29, and 31: Kennedy teaches a signal processor, an amplifier, a digital converter ("reference to a recording device 33 should be understood to include signal transmission and reception devices where the signal information is, at some point, transferred by radiowaves or fiber optics", see col. 4, ll. 49-52). Kennedy does not teach a plurality of electrodes. However, Howard teaches a device (see figs. 17 and 21b), comprising a catheter (electrode support shaft) 137; and a plurality of electrode (microelectrodes) 135a that have a diameter smaller than 10 micrometers ("each bipolar neuron-monitoring microelectrode 135A is constructed of a pair of closely juxtaposed electrical contacts 136. In addition, Howard teaches a method of sensing the activity of neural tissue or stimulating neural tissue (the device has a dual purpose electrode assembly which is used for both neuron-monitoring and detecting electrical signals to/from the patient's brain, see col. 1, lines 15-16 and col. 7, lines 44-60), comprising placing a plurality electrode 135A into a specific regions of a patient's brain, the electrode diameter being smaller than 10 micrometers (see col. 26, lines 12-19); and monitoring/providing a signal on the electrode by way of a wire connected to the electrode, wherein the signal is indicative of/stimulates the electrical brain activity of the neural tissue (see col. 7, lines 40-60); wherein the electrode comprises a sensing end, the sensing end of the electrode being placed in the blood vessel proximate to the neural tissue (see fig. 2, 8, 10, or 11A). Therefore, it would have been obvious for one

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of ordinary skill in the art at the time the invention was made to combine the Howards plurality of electrodes 135a and the size of Kennedy's electrode 10 in order to place an electrode in the brain or other neural areas without causing significant trauma to the body or other deleterious effects (see Kennedy, col. 3, ll. 5-9).

6. Claims 6-8, 17, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy in view of Howard, as applied to claims 16 above, and further in view of Lieber et al, US 2002/0117659 A1 ("Lieber").

Claims 6-8, 17, and 22-24: Neither Kennedy nor Howard explicitly teach nano-electrode(s) having a nano wire and a micro-wire. However, Lieber teaches nano-sensors comprising nano-electrodes 36 (see fig. 1a and paragraph 133) connected to nanowire 38 and electrical connections 22 (see fig. 1a and see paragraph 135). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kennedy's microelectrodes 135A in order to have electrodes that are of sufficient size to be placed near brain tissue.

7. Claims 9 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy in view of Howard and Lieber, as applied to claims 6 and 22 above, and further in view of Imram, US 5,391,147 A ("Imram").

Claims 9 and 25: Howard and Lieber do not teach a cup-like end to nano-electrodes. However, a cup-like end to an electrode is a well-known structure to electrodes. For example, Imram teaches a catheter comprising an electrode 221 having a cup shaped

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end (see fig. 19 and col. 8, lines 47-52). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Howard's electrode 135A to have a cup shaped end in order to accurately sense the activity of neural tissue.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy, as applied to claim 12 above, and further in view of over Hoek, US 6,615,067 B2 ("Hoek").

Claim 13: Kennedy does not teach a Schmitt trigger. However, use of a Schmitt trigger for converting analog signals to digital signals is well known in the art. For example, Hoek teaches a Schmitt trigger 307 connected to a filter 306 (see col. 6, lines 24-29). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kennedy's recording device 33 to include a Schmitt trigger in order to have accurate digital processing of an electrode signal.

9. Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy, as applied to claim 1 above, and further in view of Rise, US 6,374,140 B1 ("Rise").

Claims 32-36: Kennedy does not teach the claimed subject matter. However, the claimed subject matter relates well-known electrode signal processing techniques in the art. For example, Rise teaches a device, comprising: a sensor 20 with an electrode for measuring electrical activity of the brain, a signal processor 30 including a filter 200 for filtering the signal received from the electrode (see col. 5, lines 24-34). The signal

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processor 30 performs extraction and pattern recognition of the signal to determine a brain state, i.e. seizure or normal brain activity (see col. 30-48). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kennedy's device to provide processing of the signal from the electrodes in order identify brain activity and detect seizure.

10. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy, as applied to claim 39 above, and further in view of Gielen et al, US 2001/0014820 A1 ("Gielen").

Claim 40: Kennedy does not teach the electrode 10/26 is less than 1 micron in diameter. However, Gielen teaches a micro-electrode 74 less than one square micron in surface area (see paragraph [0031]). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kennedy's electrode 10/26 in order to obtain recordings from single cell activity, such as neural tissue (see Gielen paragraph [0006]).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,629,990 B2, US 6,853,075 B2, and US 6,301,492 B1 each teach electrodes less than 5 microns or nano-size electrodes. The Examiner suggests reviewing these patents before responding to the present Office Action.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735



NN

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